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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/531,851	03/20/2000	William Pendergast	36780028US04	6061

27194 7590 08/25/2004

HOWREY SIMON ARNOLD & WHITE, LLP  
C/O M.P. DROSOS, DIRECTOR OF IP ADMINISTRATION  
2941 FAIRVIEW PK  
BOX 7  
FALLS CHURCH, VA 22042

EXAMINER

OWENS JR, HOWARD V

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/531,851

**Applicant(s)**

PENDERGAST ET AL.

**Examiner**

Howard V Owens

**Art Unit**

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12-15, 18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-15, 18 and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

***Response to Arguments***

The following is in response to the amendment filed 12/18/03:

An action on the merits of claims 12-15, 18 and 19 is contained herein below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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**Claim Rejections - 35 USC § 102**

The rejection of claim 11 under 35 U.S.C. § 102(b) as being anticipated by Gorodeski et al. (Gorodeski), American J. of Physiol., Vol. 268, C1215-26 has been overcome through applicant's cancellation of the claim.

**Claim Rejections 35 U.S.C. 103**

Applicant's arguments filed have been fully considered but they are not persuasive, the rejection of claims 12-15, 18 and 19 under 35 U.S.C. § 103 as being unpatentable over Gorodeski et al. (Gorodeski), American J. of Physiol., Vol. 270, C1715-25 is maintained for the reasons of record.

Claims 12-15, 18 and 19 are drawn to a method of affecting the properties of the cervical and vaginal mucosa comprising administering an effective amount of a composition comprising dinucleoside phosphate compounds as purinergic agents.

Claims 20 and 21 are drawn to a method of stimulating cervical and vaginal secretions using diuridine tetraphosphate.

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Gorodeski teaches that ATP, a purinergic agent, can acutely and reversibly modulate the paracellular permeability of cultures of human cervical cells, moreover, that ATP, when present externally on the cervix in vivo can affect the transudation or secretion of fluid from the blood into the cervicovaginal canal which would clearly alleviate dry conditions.

Gorodeski teaches that nucleotides which have a pyrimidine base such as UTP also affect the modulation of these fluids into the cervicovaginal canal (see C1218-C1219); however, Gorodeski does not explicitly teach the use of dinucleoside phosphates of adenosine or uridine. As the nucleotide compounds of the inventions only differ by the duplication of either the pyrimidine or purine base in the compound (or an additional phosphate in the case of diuridine tetraphosphate), in the absence of a verified showing of unexpected properties, there is no invention seen in the claimed product over the compounds of the cited prior art wherein the use of purine/pyrimidine phosphate compounds have been set forth to modulate cervicovaginal fluids. Novelty alone does not constitute invention, *In re Lincoln et al.*, 29 C.C.P.A. 942,\*; 126 F.2d 477; 53 U.S.P.Q. (BNA) 40.

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to use a purinergic agent to affect the properties of the cervical mucosa.

A person of ordinary skill in the art would have been motivated to use a purinergic agent to affect the properties of the cervical mucosa given that the prior art has recognized that nucleotide purinergic agents can affect the transudation or secretion of fluid from the blood into the cervicovaginal canal.

Applicant has cited Luthje, et al. Eur. J. Biochem. as a showing of unexpected properties for the use of a dinucleotide over a mononucleotide. In order for applicant to provide a showing of an unexpected result, it must be one not recognized in the prior art. Since this showing was demonstrated prior to applicant's filing, the prior art contemplated the use of a dinucleotide over a mononucleotide, thus it was expected that a dinucleotide form of a compound

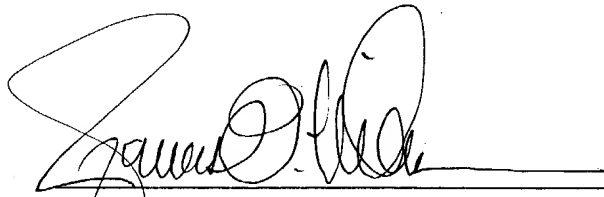
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would be more stable and therefore more useful in the prior art. Moreover, the Luthje provides additional motivation to one of skill in the art to use a dinucleotide.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Howard V. Owens  
Patent Examiner  
Art Unit 1623



James O. Wilson  
Supervisory Patent Examiner  
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (571) 272-0658. The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner signing this action, James O. Wilson can be reached on (571) 272-0661.